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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/035,753 | 12/21/2001 | Ronald G. Udell | SGTI-40565 | 3723 |

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MINNEAPOLIS, MN 55402-1498

EXAMINER

MCINTOSH III, TRAVISS C

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1623

DATE MAILED: 11/12/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

Office Action Summary

Application No.

10/035,753

Applicant(s)

UDELL ET AL.

Examiner

Traviss C McIntosh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,5,11,16 and 17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,5,11,16 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

The Amendment filed on August 14, 2003 has been received, entered into the record, and carefully considered. The following information provided in the amendment affects the instant application by:

Claims 1 and 11 have been amended.

Claims 2-3, 6-10, and 12-15 have been canceled.

Claims 16 and 17 have been added.

Arguments submitted affect the instant application by:

112 1st paragraph rejection: which has been withdrawn due to applicant's amendments.

103(a) rejection: which has been maintained for reasons of record.

The text of those section of title 35, US Code not included in this action can be found in a prior Office Action.

An action on the merits of claims 1, 4-5, 11, and 16-17 is contained herein below.

Claim Rejections - 35 USC § 103

Claims 1, and 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Seikagaku et al. (JP 61000017A) (of record), Nayak et al (US Patent 5,989,535) (newly cited), and Yano et al. (US Patent 4,443,459) (of record).

Claim 1 of the instant application is drawn to an orally administered soft gelatin capsule comprising hyaluronic acid having a dosage of between 35 to 45 mg. and a molecular weight of

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between 50,000 – 200,000 daltons. Claim 4 provides the composition additionally includes beeswax. Claim 5 provides that the composition additionally includes rice bran oil.

Seikagaku discloses a hyaluronic acid composition wherein the hyaluronic acid has a molecular weight of between 4,000 – 2,000,000 daltons and the dosage is 25mg – 5g a day (p.o.) (per os, or by mouth). The advantage of the hyaluronic acid composition of Seikagaku is it has tissue restoration effects (thus improving human skin health) (abstract). Moreover, the hyaluronic acid preparation of Seikagaku et al. is taught to be effective in various formulation types, such as granules, particles, powder, tablet, capsule, syrup, suspension, liquid, etc. It is taught to use organic or inorganic and solid or liquid carriers or diluents suitable for oral administration. Moreover, Seikagaku et al. teach to use carriers for their hyaluronic acid such as water, gelatin, lactose, starch, magnesium stearate, talc, animal or plant fats and oils (rice bran oil is a plant oil), benzyl alcohol, gum, polyalkylene glycol, petroleum resin, coconut oil, lanolin, and all other carriers usable in medical drugs. In addition, stabilizers, wetting agents, emulsifiers, and salts may be used as an auxiliary drug component (page 5, 5th full paragraph). What is not taught is the specific use of a soft gel capsule or the addition of beeswax and/or rice bran oil.

Yano et al. teach of a pharmaceutical composition comprising an active ingredient and diluents or carriers wherein the diluents or carriers can be beeswax and rice bran oil. Yano et al. additionally teach that the composition may be in various forms such as soft capsules, hard capsules, granules, and tablets (column 4, line 60 – column 5, line 5).

Nayak et al. teach a composition which can be in the form of a soft gelatin capsule which includes polymers, such as hyaluronic acid (column 3, lines 47-52 and column 4, lines 9-11, also, claims 1 and 13).

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Seikagaku, Yano et al., and Nayak et al. because Seikagaku teach an orally administered hyaluronic acid composition, Yano et al. teach of a soft gel capsule with beeswax and/or rice bran oil, and Nayak et al. teach hyaluronic acid in a soft gel capsule. The limitations as taught by Yano et al. are disclosed as being known in the art of pharmaceutical compositions as common forms of diluents and carriers. One would be motivated to incorporate the hyaluronic acid of Seikagaku into the beeswax and rice bran oil soft gelatin capsule of Yano et al. because Nayak et al. teaches hyaluronic acid can be administered via a soft gel capsule, and Seikagaku teaches various formulation types may be made, such as a capsule. Moreover, it is noted that applicants use of beeswax or rice bran oil is not seen as critical, as these are merely mentioned as ingredients added during the method of making the composition. Additionally, one would be motivated to use an oral composition of hyaluronic acid whereby one would avoid the use of topical cosmetics, which frequently contain scents and additives not always pleasing to consumers, and injections, which cause pain and discomfort for the majority of consumers, as the main form of administration. In re Peterson (Fed. Cir. 2003). "A prima facie case of obviousness typically exists when the ranges of a claimed composition overlap the ranges disclosed in the prior art. E.g., In re Geisler, 116 F.3d 1465, 1469, 43 USPQ2d 1362, 1365 (Fed. Cir. 1997); In re Woodruff, 919 F.2d 1575, 1578, 16 USPQ2d 1934, 1936-37 (CCPA 1976); In re Malagari, 499 F.2d 1297, 1303, 182 USPQ 549, 553 (CCPA 1974)."

Applicant's arguments directed to the composition were drawn to the fact that Seikagaku did not teach a soft gelatin capsule with hyaluronic acid. Nayak teaches soft gel capsules of hyaluronic acid.

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Claims 11 and 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Seikagaku et al. (JP 61000017A) (of record), Nayak et al (US Patent 5,989,535) (newly cited), and Yano et al. (US Patent 4,443,459) (of record) as applied to claims 1, and 4-5 above.

Claim 11 is drawn to a method of improving human skin health comprising administering the composition as set forth supra to a patient.

The teachings of Seikagaku, Nayak, and Yano are set forth supra in regards to the composition. Moreover, Seikagaku teach their composition to be effective against malignant melanoma (which is seen to be a method of improving skin health) (page 6, 3rd full paragraph). The composition is obvious, as set forth supra, and the method of improving the health of the skin of a patient by administering hyaluronic acid is known. One would be motivated to make a soft gel capsule and administer it to a patient to improve the health of the skin because hyaluronic acid is taught to be effective in soft gel capsules, taught to be effective in the dosage range claimed, and taught to be effective against melanoma.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

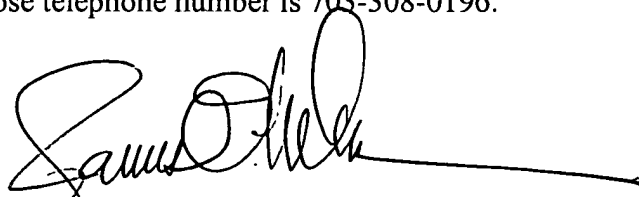
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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C McIntosh whose telephone number is 703-308-9479. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



James O. Wilson
Supervisory Patent Examiner
Art Unit 1623

Traviss C. McIntosh III
November 5, 2003